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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,296	07/01/2003	Sarah Rose Hertel	125736 (SPLG 1015)	5583
45436	7590	10/05/2007	EXAMINER	
DEAN D. SMALL			KISH, JAMES M	
THE SMALL PATENT LAW GROUP LLP				
611 OLIVE STREET, SUITE 1611			ART UNIT	
ST. LOUIS, MO 63101			PAPER NUMBER	
			3737	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/611,296	<b>Applicant(s)</b> HERTEL ET AL.	
	<b>Examiner</b> James Kish	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed April 9, 2007 have been fully considered but they are not persuasive.

Applicant argues that the cited prior art fails to teach "correlating a relative metabolic activity to an abnormality based on a threshold value." Applicant states, "Although both Suddharth and the method recited in claim 1 use threshold data, the threshold data is not the same. Namely, Suddarth uses threshold data that allows monitoring or evaluating metabolic data or evaluating a tumor using the metabolic data." Therefore, Applicant agrees that Suddarth teaches correlating the relative metabolic activity to the abnormality based on a threshold. The claim language does not specify what the threshold is or how it is used. Correlating the metabolic activity in a broad and reasonable interpretation can mean that the evaluated metabolic activity is determined to stem from the abnormality within the ROI of the structural image. Therefore, the combination of Gagnon, Shao and Suddarth teaches the limitations of the independent claims.

Therefore, the Office Action dated January 18, 2007 still stands and is repeated below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-6, 8, 10, 12, 14-15, 17, 19-20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon et al.'777 (US Patent No. 6,787,777) in view of Shao et al.'142 (US Patent No. 6,928,142), further in view of Suddarth et al. (US Patent No. 7,011,814). Gagnon et al.'777 discloses the use of positron emission tomography (PET) and single photon emission computed tomography (SPECT) (column 1, lines 10-15). Also disclosed is the knowledge that while SPECT provides structural data, which would be beneficial to use to localize a region of interest (ROI) for purposes of image registration with a PET, or function, image. It is stated as an example that in oncology, this could be used to assess lesion progression and treatment effectiveness (column 2, lines 33-49). However, Gagnon et al.'777 does not discuss how the selection process is performed. Shao et al.'142 teaches a computer workstation for controlling the imaging system (see Abstract). Via this computer, the operator manually selects a ROI of the subject on an X-ray image (column 7, lines 41-44). By manually selecting the ROI, this region is defined by having a particular area or volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the selection process taught by Shao et al.'142 in the registration discussed by Gagnon et al.'777 to provide an easy system with which the operator can select a ROI.

While Gagnon discusses the use of PET imaging to acquire metabolic information, there is no explicit discussion of correlation of relative metabolic activity

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with an abnormality based on a threshold value within the PET image. However, Suddarth teaches analyzing metabolized glucose data by comparing the data to absolute threshold data established from population norms or to relative data either normal or tumor data taken on the subject previously. The data can be used in a quantitative manner to establish concentration, quantity, rates, speed of the biochemical cycle, and the like. See column 19, lines 34-42; column 20, lines 20-43; and column 24, line 61 through column 25, line 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the analyzing steps proposed by Suddarth in the system of Gagnon in order to determine whether tissue is malignant column 7, lines 1-6).

Claims 2, 4, 7, 11, 13, 16, 21-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon et al.'777 in view of Shao et al.'142, further in view of Suddarth et al.'814 as stated in the rejection of claims 1, 3, 5-6, 8, 10, 12, 14-15, 17, 19-20, 23 and 25 above, and further in view of Townsend et al.'476 (US Patent No. 6,490,476). Gagnon et al.'777 teaches registering PET images with SPECT images in order to determine metabolic activity of abnormalities, such as lesions. Shao et al.'142 teaches manual selection of a ROI via a computer workstation. However, neither Shao nor Gagnon discuss an order of retrieving images. Townsend et al.'476 teaches the CT scan as being acquired before the PET scan, following a 60 minute uptake period (column 13, lines 19-21). Townsend also teaches scaling of the PET pixel values to display them with the same pixel size as the CT images (column 14, lines 10-12). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to use this order of operation as taught by Townsend in acquiring the images for the registration of Shao and Gagnon to allow the operator to select the ROI on the CT scan, or first image.

With regard to claim 7, Townsend et al.'476 discloses a method of discrimination between relevant and irrelevant metabolic activity by PET-CT registration (column 3, lines 30-40).

With regard to claim 13, Townsend et al.'476 discloses a method of interpolating the lower resolution PET image on to the higher resolution CT image for image fusion (column 14, lines 20-25).

With regard to claim 24, see figure 10A, which a CT image of primary lung cancer.

Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnon et al.'777 in view of Shao et al.'142, further in view of Suddarth et al.'814 as stated in the rejection of claims 1, 3, 5-6, 8, 10, 12, 14-15, 17, 19-20, 23 and 25 above, and further in view of Ferrant et al.'762 (US Patent No. 6,597,762). Gagnon et al.'777 teaches registering PET images with SPECT images in order to determine metabolic activity of abnormalities, such as lesions. Shao et al.'142 teaches manual selection of a ROI via a computer workstation. However, neither Shao nor Gagnon discuss using a specific software tool, such as Advanced Lung Analysis, for determination purposes. Ferrant et al.'762 teaches the use of CT Advanced Lung Analysis for the automatic

segmenting and sizing of lung lesions that have been identified by a radiologist (column 1, lines 12-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize software for automatic segmenting and sizing to provide tremendous capability for radiologists to identify lesions in two or three dimensional views (column 1, lines 32-34).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

  
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